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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/175,713	10/20/98	HERRMANN S	GI-5302-CON

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EXAMINER	
ANDRES, J	
ART UNIT	**PAPER NUMBER**
1646	12

DATE MAILED: 05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/175,713	HERRMANN ET AL.	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 19-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14, 17, 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 12 February 2001 in paper no. 11 is acknowledged. Claims 1-47 are pending in this application. Claims 15, 16, and 19-47 are withdrawn from consideration as being drawn to a non-elected invention. The restriction requirement of paper no. 4, 14 December 1999, is made FINAL. This application contains claims drawn to an invention nonelected in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

3. The objection to the specification is withdrawn in response to Applicant's amendment.

4. The rejection of claims 1-14, 17, and 18 as indefinite in the use of laboratory names is withdrawn in response to Applicant's arguments.

5. The rejection of claims 1, 2, 6-14, 17, and 18 as indefinite in the recitation of "amino-terminal-modified" is withdrawn in response to Applicant's amendment to the claims.

6. The rejection of claims 1, 5, and 10-14 under 35 U.S.C. 102(e) as anticipated by Pelus et al. and Talmadge et al. is withdrawn in response to Applicant's amendment.

7. The rejection of claim 5 under 35 U.S.C. 102(a) as anticipated by Proudfoot et al, is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained/New Grounds of Rejection

8. The rejection of claims 14, 17, and 18 under 35 U.S.C. 112, first paragraph, as lacking sufficient written description is maintained. Applicant argues that what is required is that an applicant convey with reasonable clarity that he or she was in possession of the claimed invention. Applicant argues that the presentation of four separate examples satisfies this requirement. Applicant cites *In re Gosteli* and *Vas-Cath, inc. v. Mahurkar*.

Applicant's arguments have been fully considered but have not been found to be persuasive. The Examiner agrees that Applicant has described a method for producing four amino-terminally-modified proteins. Such methods are standard in the art. As stated in the previous office action, however, Applicant has disclosed the functional characteristics of one species, while the claims are drawn to a genus of modified chemokines.

In determining that two species of chemical compound were insufficient to describe a genus, *In re Gosteli* does not set forth requirements for written description. *Vas-Cath, Inc. v. Mahurkar* uses the phrase "reasonable clarity" and explains that the purpose of written description is to convey to those of skill that he or she was in possession of the claimed invention at the time of filing. The disclosure of how to make four examples and of the functional characteristics of one does not serve to convey with "reasonable clarity" that Applicant was in possession of the invention as broadly claimed. Applicant has disclosed the functional characteristics of one species. As stated in the previous Office Action, there is insufficient guidance to allow one of skill to identify other species that would have the same functional characteristics as the disclosed species. Thus Applicant has not described the essential

characteristics of the claimed genus. USPTO Written Description guidelines state (Federal Register vol. 66, no., January 6, 2001):

"Satisfactory disclosure" ... depends on whether one of skill would recognize that the Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus...For inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species.

Here, the chemokines are not structurally related, the claimed modifications are not structurally related, and the claims, since they are drawn to compositions comprising the modified chemokines, are not limited to particular modified chemokines, and, as discussed in the previous office action, the art is unpredictable. Further, claims 6-9 encompass sequence variants. The disclosure of the characteristics of one species within the scope of the claims is thus insufficient to describe with "reasonable clarity" the genus as broadly claimed. Applicant has described no "necessary common attributes or feature possessed by the members of the genus". Further, the identification of four closely related species as members of such a diverse genus does not provide compensatory guidance by which one of skill might identify other members with very different structural characteristics. No parameters or features are described that these closely related species would have in common with unrelated structures by which one of skill could identify them as members of the same genus. Thus one of skill in the art would not conclude that Applicant had described the characteristics of the claimed genus.

9. The rejection of claims 1-14, 17, and 18 as lacking enablement commensurate with the scope of the claims is maintained. Applicant argues that "as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, the enablement requirement of 35 U.S.C. §112 is satisfied".

Applicant further argues that the test is not whether any experimentation is necessary. Applicant additionally argues that working examples for the expression and purification of four modified chemokines are provided, as well as examples of the use of modified chemokines. Applicant concludes that the examples are detailed enough to "inform one of ordinary skill in the art that the claimed genus can be used in the context of a specific example without undue experimentation". Applicant further argues that the invention as claimed does not require knowledge of structural and functional characteristics.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated above, the generation of the modified chemokines is art-standard. Applicant has not, however, provided sufficient guidance for one of skill to use the invention commensurate with the scope of the claims. Applicant has provided working examples for one modified chemokine. The claims, however, encompass many different and structurally varied molecules, including sequences with internal variations, as claimed in claims 6-9. The disclosure of the functional properties of one species thus does not bear a reasonable correlation to the scope of the claims, which encompass up to 50 different chemokines with distinct structures and three different modifications, more than one of which may be present on the molecule. Since, as taught by Proudefoot et al., cited in the previous office action, the effects of such modifications are unpredictable, one of skill in the art would not be able to predict which, if any, of the many species claimed would be functional: the teachings of Proudfoot et al. would lead one of skill to predict precisely the opposite outcome of what is instantly claimed. Thus the identification of one member of this diverse genus does not provide sufficient guidance by which other species that would function as claimed could be identified; it is clear that the results of the claimed

modification are not predictable. Thus, contrary to Applicant's assertion, other information as to the characteristics of functional species would be required for one of skill to predictably use the invention as broadly claimed. MPEP §2164.03 states:

...if one skilled in the art cannot readily anticipate the effect of a change within the subject matter to which that claimed invention pertains, then there is lack of predictability in the art...in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. This is because it is not obvious from the disclosure of one species, what other species will work.

Since there are many possible encompassed species, since Applicant has disclosed the functional characteristics of only one, and since Applicant has not provided any guidance by which other functional species might be identified, and since the art teaches that the outcome of such modifications is not predictable, one of skill in the art would not be able to predictably identify species that meet the limitations of the claims. It is the lack of ability to predict which of the many possible species that meet the limitations of the claims would actually be functional that renders the required experimentation undue.

10. The rejection of claims 6-9 as indefinite in the recitation of "amino-terminal fragment" and "stringent conditions" is maintained. Fragments are not defined on p. 20; examples are presented but there are no actual limitations as to what constitutes a fragment. Similarly, what is presented on p. 22 is an example, not a definition, of stringent conditions.

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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